REMARKS

1. Status of claims

Claims 1-4 and 14-15 are pending and under consideration; claims 5-13 are pending but have been withdrawn. Claims 16-23 were previously canceled and claims 24-25 are newly canceled.

2. Support for amendment

The above amendment finds support in the specification at p. 4, lines 22-24 and in prior claims 24-25. No new matter has been added by this amendment.

3. Claim rejections under 35 U.S.C. § 102(b)

The Examiner rejected claims 1-4 and 15 as being anticipated by Fumelli, *et al.*, *Soc. Invest. Dermatol.* 2000, 115:5, 835-841 ("Fumelli"). Applicants traverse this rejection.

As Applicants have previously discussed, Fumelli teaches the administration of carboxyfullerenes, such as C3, to keratinocytes as preventing UVB-induced inhibition of keratinocyte proliferation and UVB-induced keratinocyte apoptosis (Materials and Methods, pp. 835-836, and Results, pp. 838-839 and Figs.2-5). However, Fumelli explicitly teaches that it is unknown whether carboxyfullerenes would be effective in treating dermatological conditions in skin. Specifically, at p. 840, right column, Fumelli says, "exploitation of the carboxyfullerene molecule *could* lead to the definition of new therapeutic strategies in the prevention of both skin aging and tumorigenesis" (emphasis added). In other words, Fumelli does not teach a method of treating a dermatological condition; Fumelli and her coauthors, who are persons of ordinary skill in the art, admitted they did not teach such a method. Because they fail to teach a method of treating a dermatological condition, Fumelli *et al.* also fail to teach the concentrations and carriers.

In contrast, the present claims recite methods of treating dermatological conditions involving particular concentrations and carriers. Therefore, Fumelli does not teach every element of the present claims and thus cannot anticipate them. Applicants therefore request this rejection of claims 1-4 and 15 be withdrawn.

4. Claim rejections under 35 U.S.C. § 112, first paragraph

The Examiner rejected claims 1-4, 14-15, and 24-25 as not being enabled for preventing dermatological conditions. In light of the above amendment, these claims recite a method for treating a dermatological condition. Therefore, Applicants submit the basis for this rejection has been removed and request it be withdrawn.

Also, Applicants submit that the Examiner's statement that "Fig. 1 represents nothing at all" (Detailed Action mailed August 11, 2008, p. 6) is inaccurate, especially in view of the color drawing of Figure 1 which Applicants petitioned the Office to accept on December 5, 2007. (A decision on the petition has not been made by the Office as of the date shown below). However, regardless of whether a color or a black-and-white version of Figure 1 is considered, Figure 1 in light of Example 1, pp. 23-24 of the specification, shows peeling and/or blistering of untreated sunburned skin (outside the notional box), but very little if any peeling and/or blistering of sunburned skin treated according to a method of the present invention (inside the notional box).

5. Claim rejections under 35 U.S.C. § 103(a)

First, the Examiner rejected claims 1-4 and 14-15 as being unpatentable over Fumelli in view of Hirsch, *et al.*, US 7,070,810 ("Hirsch"). Applicants traverse this rejection.

First, Hirsch was filed on February 14, 2003 and published as US 2003/0180491 on September 25, 2003. The present application claims priority to U.S. Pat. Appl. 60/461,914, filed on April 10, 2003. Therefore, Hirsch can only be prior art under 35 U.S.C. § 102(e). Both

Hirsch and the present invention were, at the time the present invention was made, owned by or subject to an obligation of assignment to C Sixty, Inc. Therefore, according to 35 U.S.C. § 103(c), Hirsch does not preclude the patentability of the present claims under 35 U.S.C. § 103.

To the extent that Fumelli alone can be applied against the claims under 35 U.S.C. § 103(a), under recent United States case law, specifically, *KSR International Co. v. Teleflex Inc.,* 550 U.S.—, 82 USPQ2d 1385 (2007), regardless of the particular rationale used, a finding of unpatentability under 35 U.S.C. § 103 requires an Examiner to show, among other findings, a finding that one of ordinary skill in the art could have pursued known options or combined known elements *with a reasonable expectation of success*. At most, the person of ordinary skill in the art, in attempting to modify the teachings of Fumelli, would have had an *unreasonable* expectation of success at arriving at the presently claimed invention.

Fumelli has been discussed above. Particularly, Fumelli teaches the administration of carboxyfullerenes to keratinocytes as preventing UVB-induced inhibition of keratinocyte proliferation and UVB-induced keratinocyte apoptosis; however, Fumelli has failed to teach the treatment of a disease in the skin of a mammal (p. 840, right column). As authors of a published scientific paper, Fumelli and her coworkers are clearly persons of ordinary skill in the art. Therefore, from Fumelli's statement "exploitation of the carboxyfullerene molecule *could* lead to the definition of new therapeutic strategies in the prevention of both skin aging and tumorigenesis" (emphasis added), the person of ordinary skill in the art would recognize that Fumelli had not defined a method of treating dermatological conditions and provided no guidance as to what modifications of Fumelli's teachings would be required to define a method of treating dermatological conditions. Plainly, the lack of definition and lack of guidance give

the person of ordinary skill in the art an *unreasonable* expectation of success at modifying the teachings of Fumelli to arrive at the present invention.

In light of the teachings of Fumelli and the knowledge of the person of ordinary skill in the art, such a person could *not* have had a reasonable expectation that a composition comprising a substituted fullerene comprising a fullerene core (Cn) and at least one of the structural features (i)-(iv) recited by claim 1 would be effective in treating a dermatological condition in the skin of a mammal. Therefore, Fumelli fails to render the present claims unpatentable under any standard requiring a finding of a reasonable expectation of success set forth by the court in *KSR*.

In addition, claims 1-4 and 14-15 now incorporate limitations previously found in claims 24-25. Because the Examiner did not reject prior claims 24-25 as being unpatentable over Fumelli and Hirsch, claims incorporating their limitations must, as a matter of logic, also be patentable over Fumelli and Hirsch.

For at least one or more of the following reasons, claims 1-4 and 14-15 are patentable over Fumelli and this rejection should be withdrawn.

The Examiner also rejected claims 24-25 as being unpatentable over Fumelli in view of Dugan, *et al.*, US 2003/0162837 ("Dugan"). Insofar as it applies to claim 1, Applicants traverse this rejection.

The limitations recited by prior claims 24-25 relate to a composition having a substituted fullerene concentration from about 0.01 wt% to about 5 wt% and a composition further comprising at least one carrier that may be water, respectively, wherein the composition is used in the method of treating a dermatological condition recited by claim 1.

As stated above, a finding of unpatentability under 35 U.S.C. § 103 requires an Examiner to show, among other findings, a finding that one of ordinary skill in the art could have pursued

known options or combined known elements *with a reasonable expectation of success*. In addition, the Court in *KSR* stated there must be an apparent reason to combine known elements, and further, "To determine whether there was an apparent reason to combine the known elements in the way a patent claims, it will often be necessary to look to interrelated teachings of multiple patents; to the effects of demands known to the design community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art." The person of ordinary skill in the art, in attempting to apply the teachings of Dugan to those of Fumelli, would have had *no apparent reason* to combine elements of the references, and therefore, he or she would have had an *unreasonable* expectation of success at arriving at the presently claimed invention.

Fumelli has been discussed above. Particularly, Fumelli teaches the administration of carboxyfullerenes to keratinocytes as preventing UVB-induced inhibition of keratinocyte proliferation and UVB-induced keratinocyte apoptosis; Fumelli also teaches that it has failed to define a method of treating a dermatological condition (p. 840, right column).

Dugan relates to the use of carboxyfullerenes as neuroprotectants (Abstract). Therefore, Fumelli and Dugan are directed to administering fullerenes to different cell types from different organs. The person of ordinary skill in the art will understand Dugan's teachings regarding neuroprotection do not overcome Fumelli's explicit admission that Fumelli and coworkers did not define a method of treating dermatological conditions. Therefore, there is no apparent reason to combine the references, and even if there were, their combination would fail to overcome Fumelli's explicit admission that Fumelli and coworkers did not define a method of treating dermatological conditions.

Therefore, there is no apparent reason to combine the teachings of Fumelli and Dugan, and, even if an apparent reason existed, any possible combination of the references fails to render the present claims unpatentable under any standard requiring a finding of a reasonable expectation of success set forth by the court in *KSR*. Therefore, claim 1, and all claims dependent thereon, are patentable over Fumelli and Dugan and this rejection should be withdrawn.

6. Conclusion

Applicants submit all pending claims are in condition for allowance. The Examiner is invited to contact the undersigned patent agent at (713) 934-4065 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

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